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XIX WORKSHOP
MÉTODOS RÁPIDOS Y AUTOMATIZACIÓN EN MICROBIOLOGÍA ALIMENTARIA

GFSI desde la visión del Food Safety Modernization Act (FSMA)

UAB – MRAMA 2020

CONTENIDO

Food Safety Modernization Act

Adaptación de los esquemas GFSI a las necesidades de FSMA

PCQI

PORQUÉ DE ESTA APROXIMACION?

Establecer vías de aplicación a los esquemas de certificación GFSI

Entender las obligaciones, responsabilidades y consecuencias del PCQI

FOOD SAFETY MODERNIZATION ACT

https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma

Según datos FDA cada año…
… 1 de cada 6 personas (48M) enferma a consecuencia de ingesta de alimentos no inocuos
… 128.000 personas deben ser hospitalizadas
…. 3000 mueren a causa de ello.

Es necesario un control eficiente en los alimentos a fin de prevenir cualquier situación que conlleve a la producción y posterior ingesta de alimentos no inocuos.

La FDA establece unas vías fundamentales para conseguir esta finalidad entre ellos la necesidad de establecer controles preventivos para alimentación humana que afecta tanto a empresas de EEUU como aquellas de países terceros que quieran exportar sus productos a EEUU

EL CONTROL PREVENTIVO COMO LA BASE DEL SGIA

ANALISIS DE PELIGROS

CONTROLES PREVENTIVOS (PCC's, alérgenos, limpieza, proveedores ….)

Ya no hablaremos **PCC's** como resultado del análisis de peligros y evaluación del riesgo.
Con el nuevo enfoque hablamos de "CONTROLES PREVENTIVOS" en los que se incluyen los PCC's así como otros planes específicos para controlar los peligros significativos.

PARÁMETROS / VALORES

Hablamos de PARAMETROS / VALORES en vez de LIMITES CRITICOS para reconocer que algunos controles preventivos no tienen limites críticos per se (p. ej. "superficies limpias"

Monitorización

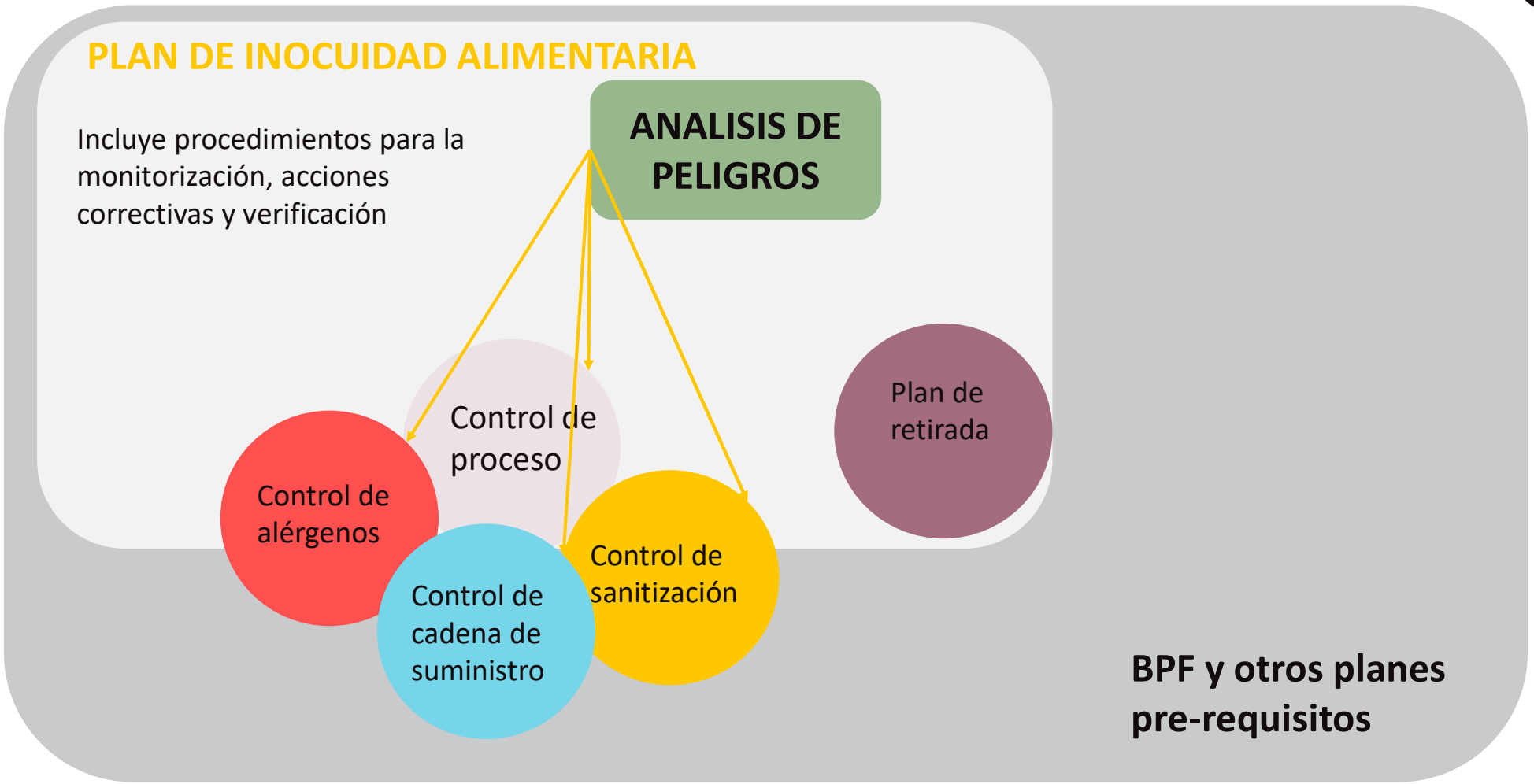
Correcciones / Acciones correctivas

EL CONTROL PREVENTIVO COMO LA BASE DEL SGIA

Peligro que requiere un control preventivo significa un peligro conocido o razonablemente previsible para el que una persona con conocimiento sobre la fabricación, procesamiento, envasado o almacenamiento seguro de alimentos, según el resultado de un análisis de peligro (que incluye una evaluación de la gravedad de la enfermedad o lesión si ocurriera el peligro y la probabilidad de que el peligro ocurra en ausencia de controles preventivos), establezca uno o más controles preventivos para minimizar o prevenir significativamente el peligro en un alimento y componentes para gestionar esos controles (como monitoreo, correcciones o acciones correctivas, verificación y registros) según corresponda a los alimentos, la instalación y la naturaleza del control preventivo y su papel en el sistema de seguridad alimentaria de la instalación.

Controles preventivos significa aquellos procedimientos, prácticas y procesos basados en el riesgo y razonablemente apropiados que una persona con conocimiento sobre la fabricación, procesamiento, empaque o almacenamiento seguro de alimentos emplearía para minimizar o prevenir significativamente los peligros identificados en el análisis de peligros que sean consistentes con la comprensión científica actual de la fabricación, procesamiento, envasado o conservación seguros de alimentos en el momento del análisis.

EL CONTROL PREVENTIVO COMO LA BASE DEL SGIA



APROXIMACION DE BRCGS A FSMA

2 THE FOOD SAFETY PLAN – HACCP

FUNDAMENTAL

The company shall have a fully implemented and effective food safety plan incorporating the Codex Alimentarius HACCP principles.

MOTIVACION DEL CAMBIO DE LA DECLARACIÓN DE INTENCIONES → *Some countries (e.g. the US) have introduced regulatory requirements that incorporate all of the HACCP processes outlined by the Codex Alimentarius but use different terminology. The specific terminology within the Standard, such as HACCP, prerequisites or critical control points, are intended to utilise the most commonly used global terminology to escribe expectations. Sites are not required to use the specific terminology of the Standard, but are expected to fully meet the requirements.*

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Food

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FDA Food Safety Modernization Act (FSMA)

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Sign-Up for FSMA Email Updates

About 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA) is transforming the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it. Congress enacted FSMA in response to dramatic changes in the global food system and in our understanding of foodborne illness and its consequences, including the realization that preventable foodborne illness is both a significant public health problem and a threat to the economic well-being of the food system.

FDA has finalized seven major rules to implement FSMA, recognizing that ensuring the safety of the food supply is a shared responsibility

Spotlight

- Draft Produce Safety Rule Guidance with At-a-Glance overviews of key points in the nine chapters. (October 2018)

APROXIMACION DE BRCGS A FSMA

2.1 THE HACCP FOOD SAFETY TEAM (EQUIVALENT TO CODEX ALIMENTARIUS STEP 1)

CLAUSE	REQUIREMENTS
2.1.1	The HACCP or food safety plan shall be developed and managed by a multi-disciplinary food safety team that includes those responsible for quality assurance, technical management, production operations, engineering and other relevant functions. The team leader shall have an in-depth knowledge of Codex HACCP principles (or equivalent) and be able to demonstrate competence, experience and training. Where there is a legal requirement for specific training, this shall be in place. The team members shall have specific knowledge of HACCP and relevant knowledge of products, processes and associated hazards. In the event of the site not having the appropriate in-house knowledge, external expertise may be used, but day-to-day management of the food safety system shall remain the responsibility of the company.
2.1.2	The scope of each HACCP or food safety plan, including the products and processes covered, shall be defined.

PCQI TRAINING

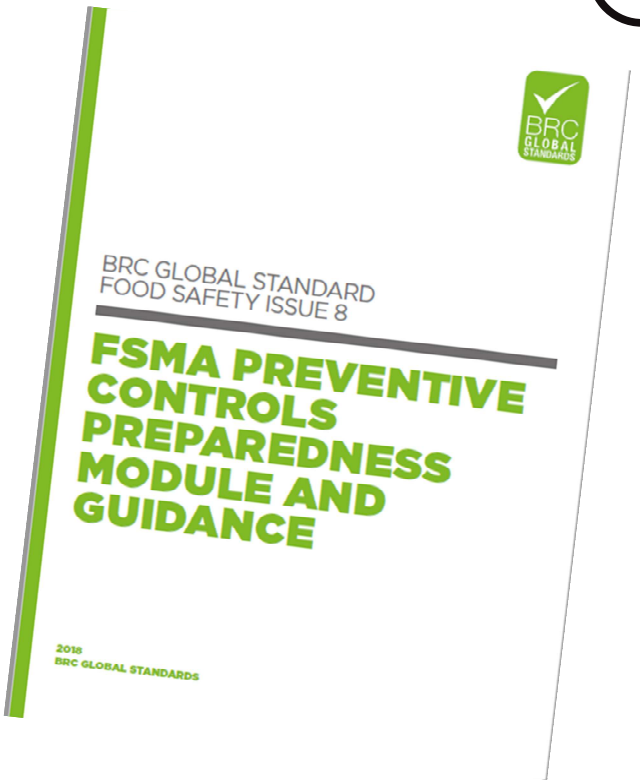
APROXIMACION DE BRCGS A FSMA

CLAUSE	REQUIREMENTS
2.7.1	The HACCP food safety team shall identify and record all the potential hazards that are reasonably expected to occur at each step in relation to product, process and facilities. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and consideration of the following types of hazard: • microbiological • physical contamination • chemical and radiological contamination • fraud (e.g. substitution or deliberate/intentional adulteration) • malicious contamination of products • allergen risks (see clause 5.3). It shall also take account of the preceding and following steps in the process chain.

APROXIMACION DE BRCGS A FSMA

Aborda los requisitos de cumplimiento en las siguientes reglas FSMA:

- Buenas prácticas de fabricación actuales, análisis de peligros y controles preventivos basados en riesgos para alimentación humana
- Buenas prácticas de fabricación actuales y análisis de peligros y controles preventivos basados en riesgos para alimentos para animales
- Estrategias de mitigación para proteger los alimentos contra la adulteración intencional
- Transporte sanitario de alimentos para humanos y animales
- Estándares para el cultivo, la cosecha, el empaque y la conservación de productos para consumo.



APROXIMACION DE BRCGS A FSMA

EJEMPLOS DE ACTIVIDADES CUBIERTAS DE ACUERO A LOS REQUISITOS LEGISLATIVOS

La empresa fabrica, procesa, envasa o gestiona alimentos para alimentación humana o animal para vender en USA

La empresa debe registrarse en la FDA como establecimiento de alimentos de acuerdo con los requisitos legislativos establecidos en la sección 415 de FD&C y volver a registrarme cada 2 años.

La empresa debe registrarse con la FDA como establecimiento de alimentos y tomar posesión física de productos alimenticios para humanos o animales con el propósito de fabricar, procesar, envasar o almacenar

La empresa debe cumplir con:

- 21 CFR Parte 117: Controles preventivos para alimentos humanos (o 21 CFR Parte 507 para alimentos de animales), y
- 21 CFR Parte 121: Estrategias de mitigación para proteger los alimentos contra la adulteración intencional, a menos que se espere.

El emplazamiento es responsable de informar sobre alimentos adulterados o mal etiquetados..

APROXIMACION DE IFS FOOD V7 A FSMA

GESTIÓN DE LA INOCUIDAD ALIMENTARIA

2.2.1.1	The basis of the company's food safety **management** system shall be a fully implemented, systematic and comprehensive HACCP **based plan**, **following the** Codex Alimentarius **principles and** any legal requirements of the production and destination countries which may go beyond such principles. The HACCP **plan** shall be specific and implemented at the production site.

2.2.1.2	The HACCP **plan** shall cover all raw materials, **packaging materials,** products or product groups as well as every process from **incoming** goods **up to** dispatch of **finished** products, including product development.

2.2.1.3	The company shall ensure that the HACCP **plan** is based upon scientific literature, **or expert advice obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities.** This **information** shall be maintained in line with **any** new technical process development.

2.2.1.4	The company shall ensure **that in the event of changes to raw materials, packaging materials, processing methods, infrastructure and/or equipment, the HACCP plan** is reviewed to assure that product safety requirements are complied with.

APROXIMACION DE IFS FOOD V7 A FSMA

GESTIÓN DE LA INOCUIDAD ALIMENTARIA

2.2.2.1	**Assemble HACCP Team:** The HACCP team shall have the **appropriate** specific knowledge and **expertise and be a multidisciplinary team which includes operational staff.**

2.2.2.2	Those responsible for the development and maintenance of the HACCP **plan** shall have an internal team leader and shall have received adequate training in the application of the HACCP principles **and specific knowledge of the product and processes.**

APROXIMACION DE IFS FOOD V7 A FSMA

GESTIÓN DE LA INOCUIDAD ALIMENTARIA

2.2.3.1	**Describe product:** A full description of the product including all relevant information on product safety shall exist, such as: -composition -physical, organoleptic, chemical and microbiological **characteristics** -legal requirements for the food safety of the product -methods of treatment, packaging, durability (shelf life) -conditions for storage, method of transport and distribution.

2.2.3.2	**Identify intended use:** The intended use of the product shall be described in relation to the expected use of the product by the end consumer, taking vulnerable groups of consumers **into account .**

APROXIMACION DE IFS FOOD V7 A FSMA

GESTIÓN DE LA INOCUIDAD ALIMENTARIA

2.2.3.3	**Construct flow diagram:** A flow diagram shall exist for each product, or product group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and **after the determination of control measures**, clearly identify each CCP and **other control measures**. In the event of any changes, the flow diagram shall be updated.

2.2.3.4	**On-site confirmation of the flow diagram:** **Representatives of** the HACCP team shall verify the flow diagram, by on-site verifications, at all operation stages **and shifts**. Where appropriate, amendments to the diagram shall be made.

2.2.3.5	**Conduct a hazard analysis for each step:** A hazard analysis shall be **conducted for all possible** and reasonably expected physical, chemical **(including radiological and allergens)** and biological hazards. **The analysis shall also include hazards linked to materials in contact with food, packaging materials and hazards related to the work environment**.. The hazard analysis shall consider the likely occurrence of hazards and the severity of their adverse health effects. **Consideration shall be given to the specific control measures that shall be applied to control each hazard.** **to control each hazard.**

SISTEMA DE GESTIÓN DE CALIDAD Y SEGURIDAD ALIMENTARIA
ANÁLISIS APPCC

2.2.3.6	**Determine critical control points and other control measures:** The determination of relevant CCPs and other control measures shall be facilitated by the application of a decision tree or other tool(s), which demonstrates a logical reasoned approach.

2.2.3.8.1 K.O.	KO N° 2: Specific monitoring procedures in terms of method, frequency of measurement or observation and recording of results, shall be established for each CCP to detect any loss of control at that CCP. Each defined CCP shall be under control. Monitoring and control of each CCP shall be demonstrated by records.
2.2.3.8.2	Records of CCP monitoring shall be **verified by a responsible person within the company and maintained for a relevant period.**
2.2.3.8.3	The operative personnel in charge of the monitoring of CCPs and other control measures shall have received specific training/ instruction.
2.2.3.8.4	**Control measures, other than CCPs, shall be monitored, recorded and controlled by measurable or observable criteria**

APROXIMACION DE IFS FOOD V7 A FSMA

GESTIÓN DE LA INOCUIDAD ALIMENTARIA

2.2.3.9	**Establish corrective actions:** In the event that the monitoring indicates that a particular CCP **or control measure other than CCP** is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any **action taken relating to non-conforming products and identify the root cause for the loss of control of CCPs**.

2.2.3.10	**Establish verification procedures:** Procedures of verification shall be established to confirm that the HACCP **plan is working correctly.** Verification of the HACCP plan shall be performed at least once a year. Examples of verification activities include: - internal audits, -analyses -sampling -**deviations** -complaints The results of this verification shall be incorporated into the HACCP **plan.**

APROXIMACION DE IFS FOOD V7 A FSMA

GESTIÓN DE LA INOCUIDAD ALIMENTARIA

2.2.3.11	**Establish documentation and record keeping** **Documentation related to the HACCP plan shall be in place. Examples of documentation include:** -hazard analysis -determination **of CCPs** and other control measures -determination of critical limits -processes, procedures **Examples of records include:** -**outcome of CCPs** and other control measures monitoring activities -observed deviations and **implemented** corrective actions

APROXIMACION DE FSSC22000 v5 A FSMA

8.5.2.2 Hazard identification and determination of acceptable levels

8.5.2.2.1 The organization shall identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment.

The identification shall be based on:

a) the preliminary information and data collected in accordance with 8.5.1;

b) experience;

c) internal and external information including, to the extent possible, epidemiological, scientific and other historical data;

d) information from the food chain on food safety hazards related to the safety of the end products, intermediate products and the food at the time of consumption;

e) statutory, regulatory and customer requirements.

NOTE 1 Experience can include information from staff and external experts who are familiar with the product and/or processes in other facilities.

NOTE 2 Statutory and regulatory requirements can include food safety objectives (FSOs). The Codex Alimentarius Commission defines FSOs as "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)".

Hazards should be considered in sufficient detail to enable hazard assessment and the selection of appropriate control measures.

8.5.2.2.2 The organization shall identify step(s) (e.g. receiving raw materials, processing, distribution and delivery) at which each food safety hazard can be present, be introduced, increase or persist.

When identifying hazards, the organization shall consider:

a) the stages preceding and following in the food chain;

b) all steps in the flow diagram;

c) the process equipment, utilities/services, process environment and persons.

8.5.2.2.3 The organization shall determine the acceptable level in the end product of each food safety hazard identified, whenever possible.

When determining acceptable levels, the organization shall:

a) ensure that applicable statutory, regulatory and customer requirements are identified;

b) consider the intended use of end products;

c) consider any other relevant information.

The organization shall maintain documented information concerning the determination of acceptable levels and the justification for the acceptable levels.

APROXIMACION DE FSSC22000 v5 A FSMA

8.5.2.3 Hazard assessment

The organization shall conduct, for each identified food safety hazard, a hazard assessment to determine whether its prevention or reduction to an acceptable level is essential.

The organization shall evaluate each food safety hazard with regard to:

a) the likelihood of its occurrence in the end product prior to application of control measures;

b) the severity of its adverse health effects in relation to the intended use (see 8.5.1.4).

The organization shall identify any significant food safety hazards.

The methodology used shall be described, and the result of the hazard assessment shall be maintained as documented information.

SOBRE PELIGROS SIGNIFICATIVOS.....

8.5.2.4 Selection and categorization of control measure(s)

8.5.2.4.1 Based on the hazard assessment, the organization shall select an appropriate control measure or combination of control measures that will be capable of preventing or reducing the identified significant food safety hazards to defined acceptable levels.

The organization shall categorize the selected identified control measure(s) to be managed as OPRP(s) (see 3.30) or at CCPs (see 3.11).

The categorization shall be carried out using a systematic approach. For each of the control measures

APROXIMACION DE FSSC22000 v5 A FSMA

CCP

3.11
critical control point
CCP

step in the *process* (3.36) at which *control measure(s)* (3.8) is (are) applied to prevent or reduce a *significant food safety hazard* (3.40) to an acceptable level, and defined *critical limit(s)* (3.12) and *measurement* (3.26) enable the application of *corrections* (3.9)

PRPO

3.30
operational prerequisite programme
OPRP

control measure (3.8) or combination of control measures applied to prevent or reduce a *significant food safety hazard* (3.40) to an *acceptable level* (3.1), and where *action criterion* (3.2) and *measurement* (3.26) or observation enable effective control of the *process* (3.36) and/or *product* (3.37)

APROXIMACION DE FSSC22000 v5 A FSMA

The organization shall categorize the selected identified control measure(s) to be managed as OPRP(s) (see 3.30) or at CCPs (see 3.11).

The categorization shall be carried out using a systematic approach. For each of the control measures selected, there shall be an assessment of the following:

a) the likelihood of failure of its functioning;

b) the severity of the consequence in the case of failure of its functioning; this assessment shall include:

   1) the effect on identified significant food safety hazards;

   2) the location in relation to other control measure(s);

   3) whether it is specifically established and applied to reduce the hazards to an acceptable level;

   4) whether it is a single measure or is part of combination of control measure(s).

8.5.2.4.2 In addition, for each control measure, the systematic approach shall include an assessment of the feasibility of:

a) establishing measurable critical limits and/or measurable/observable action criteria;

b) monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria;

c) applying timely corrections in case of failure.

The decision-making process and results of the selection and categorization of the control measures shall be maintained as documented information.

External requirements (e.g. statutory, regulatory and customer requirements) that can impact the choice and the strictness of the control measures shall also be maintained as documented information.

CATEGORIZAR DE MEDIDAS DE CONTROL

PCQI - PREVENTIVE CONTROL QUALIFIED INDIVIDUAL

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Fuente: Food and Drug Administration (FDA). 21 CFR 117.3 Definitions

Responsibilidades??

Sec. 117.180 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

1) *La preparación del plan de inocuidad alimentaria*
2) *La validación de los controles preventivos*
3) *La verificación de los registros*
4) *La reevaluación del Plan de Inocuidad Alimentaria.*

GRACIAS POR VUESTRA ATENCIÓN

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